PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Information Document Concerning the Definition of the Term "Medical Device"

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: March 26, 2003

Table of Contents

Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development

1.0 Introduction

The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities or by nations with developing regulatory programmes.

The purpose of this document is to allow a manufacturer to identify which of their products falls within the scope of a harmonized definition of the term medical device. Other documents endorsed by the Global Harmonization Task Force make use of this term.

This guidance document has been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). Comments or questions about it should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page.

2.0 Scope

This document applies to products that have a medical purpose and are subject to the work of the GHTF. It suggests a definition of the term 'medical device' that could be used as part of a global regulatory model and is based mainly upon the common ground within the established systems of member regulatory authorities. The accompanying notes indicate certain products where common ground does not yet exist.

This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices Regulatory Authorities, Conformity Assessment Bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations.

Regulatory Authorities that are developing new regulations or amending existing ones are encouraged to consider the adoption of this definition, as this will help to reduce the diversity of systems worldwide and facilitate the process of harmonization.

The regulatory requirements of some countries may not, at present, reflect the contents of this document. Regulatory Authorities with existing systems are also encouraged to consider adopting this definition.

3.0 References

Not applicable.

4.0 Definitions

Not applicable.

5.0 Harmonized definition of the term "medical device"

`**Medical device**' means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

NOTE 1: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some *in vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations.

NOTE 2: Products, which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices (see Note 3),
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but be subject to different controls.

NOTE 3: Accessories intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF guidance as applies to the medical device itself.